WE CLAIM:

1. A controlled release dosage form comprising:

a sustained release portion comprising nitrofurantoin and one or more pH dependent hydrophilic polymers; and

an immediate release portion comprising nitrofurantoin.

2. The dosage form according to claim 1 wherein the sustained release portion further comprises one or more pH independent hydrophilic polymers.

3. The dosage form according to claim 1 wherein the sustained release portion comprises two pH dependent hydrophilic polymers.

4. The dosage form according to claim 1 wherein the pH dependent hydrophilic polymer comprises one or more of cross-linked acrylic acid polymers and methacrylic acid derivatives.

5. The dosage form according to claim 4 wherein the cross-linked acrylic acid polymers comprise carboxyvinyl polymers.

6. The dosage form according to claim 5 wherein the carboxyvinyl polymer comprises one or more of Carbopol® 974P, Carbopol® 971P, and Carbopol® 934P.

7. The dosage form according to claim 5 wherein the carboxyvinyl polymer comprises a combination of Carbopol® 974P and Carbopol® 971P.

8. The dosage form according to claim 4 wherein the methacrylic acid derivative comprises one or more of Eudragit® L and Eudragit® S.

9. The dosage form according to claim 2 wherein the one or more pH independent hydrophilic polymers comprise cellulose ether.

10. The dosage form according to claim 9 wherein the cellulose ether comprises one or more of hydroxypropyl methylcellulose and hydroxypropyl cellulose. The dosage form according to claim 10 wherein the cellulose ether comprises one or more low viscosity hydroxypropyl celluloses having a molecular weight of about 80,000-100,000.

11. The dosage form according to claim 1 wherein the nitrofurantoin comprises macrocrystalline nitrofurantoin.

12. The dosage form according to claim 1 wherein nitrofurantoin has a particle size distribution with D_{90}<250 μm.

13. The dosage form according to claim 1 wherein the sustained release portion further comprises one or more pharmaceutically acceptable excipients.

14. The dosage form according to claim 1 wherein the sustained release portion comprises one or more of powder, granules, compact or tablet.

15. The dosage form according to claim 14 wherein the sustained release portion comprises a tablet.

16. The dosage form according to claim 1 wherein the immediate release portion comprises one or more of powder or granules.

17. The dosage form according to claim 16 wherein the immediate release portion comprises powder.

18. The dosage form according to claim 1 wherein the dosage form comprises a capsule.

19. The dosage form of claim 1 wherein the dosage form has a dissolution profile in which approximately eight percent to approximately twenty percent of the nitrofurantoin in the dosage form is released within one hour in an approximately 0.01N HCl solution and the majority of the remaining nitrofurantoin in the dosage form is released over seven hours in a phosphate buffer having a pH of approximately 7.5, the dissolution profile being measured using a USP apparatus 2 at a paddle speed of approximately 100 rpm and a temperature of approximately 37°C.

20. A process for the preparation of a controlled release dosage form comprising a sustained release portion and an immediate release portion, the process comprising:

preparing the sustained release portion in a process comprising blending nitrofurantoin with one or more pH dependent hydrophilic polymers;

preparing the immediate release portion by providing nitrofurantoin; and

filling the sustained release portion and the immediate release portion into the dosage form.

21. The process of claim 20 wherein preparing the sustained release portion further comprises mixing and blending the nitrofurantoin with one or more pharmaceutically acceptable excipients.

22. The process of claim 21 wherein preparing the immediate release portion further comprises blending the nitrofurantoin with one or more pharmaceutically acceptable excipients.

23. The process of claim 21 wherein the dosage form comprises a capsule.

24. The process of claim 21 wherein the immediate release portion is filled into the dosage form before the sustained release portion is filled into the dosage form.

25. The process of claim 21 wherein the immediate release portion is filled into the dosage form after the sustained release portion is filled into the dosage form.

26. The process of claim 21 wherein the nitrofurantoin in the immediate release portion comprises macrocrystalline nitrofurantoin.

27. The process of claim 21 wherein the nitrofurantoin in the immediate release portion has a particle size distribution with D_{90}<250 μm.

28. The process of claim 21 further comprising blending the sustained release portion with one or more pH independent hydrophilic polymers.

29. The process of claim 28 wherein the pH independent hydrophilic polymer comprises one or more cellulose ethers.

30. The process of claim 29 wherein the one or more cellulose ethers comprise one or more of hydroxypropyl methylcellulose and hydroxypropyl cellulose.

31. The process of claim 30 wherein the hydroxypropyl cellulose has a low viscosity and a molecular weight of about 80,000-100,000.

32. The process of claim 21 wherein the sustained release portion comprises two pH dependent hydrophilic polymers.

33. The process of claim 21 wherein the pH dependent hydrophilic polymer comprises one or more of cross-linked acrylic acid polymers and methacrylic acid derivatives.

34. The process of claim 33 wherein the cross-linked acrylic acid polymers comprises one or more carboxyvinyl polymers.

35. The process of claim 34 wherein the carboxyvinyl polymer comprises one or more of Carbopol® 974P, Carbopol® 971P, and Carbopol® 934P.

36. The process of claim 34 wherein the carboxyvinyl polymer comprises a combination of Carbopol® 974P and Carbopol® 971P.

37. The process of claim 33 wherein the one or more methacrylic acid derivatives comprise one or both of Eudragit® L and Eudragit® S.

38. The process of claim 21 wherein the sustained release portion comprises powder, granules, compact or tablet.

39. The process of claim 21 wherein the immediate release portion comprises powder or granule.

40. The process of claim 21 wherein the dosage form comprises a capsule.

41. The process of claim 21 wherein the dosage form has a dissolution profile in which approximately eight percent to approximately twenty percent of the nitrofurantoin in the dosage form is released within one hour in an approximately 0.01N HCl solution and the majority of the remaining nitrofurantoin in the dosage form is released over seven hours in a phosphate buffer having a pH of approximately 7.5, the dissolution profile

being measured using a USP apparatus 2 at a paddle speed of approximately 100 rpm and a temperature of approximately 37°C.

42. A method of treating a urinary tract infection comprising administering a controlled release dosage form, the dosage form comprising:

a sustained release portion comprising nitrofurantoin and one or more pH dependent hydrophilic polymers; and

an immediate release portion comprising nitrofurantoin.

43. The method of claim 42 wherein the dosage form has a dissolution profile in which approximately eight percent to approximately twenty percent of the nitrofurantoin in the dosage form is released within one hour in an approximately 0.01N HCl solution and the majority of the remaining nitrofurantoin in the dosage form is released over seven hours in a phosphate buffer having a pH of approximately 7.5, the dissolution profile being measured using a USP apparatus 2 at a paddle speed of approximately 100 rpm and a temperature of approximately 37°C.